

Remarks

Claims 45-69 were pending in the subject application. By this Amendment, claims 45, 50, 55, and 60 have been amended, and claims 66-69 have been cancelled. The undersigned avers that no new matter is introduced by this Amendment. Support for the new claims and amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Claim 65 remains pending but withdrawn from consideration. Accordingly, claims 45-65 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's indication that the rejection of claims 66-69 under 35 USC §112, first paragraph, as new matter, has been withdrawn.

Claims 45-64 and 66-69 are rejected under 35 USC §112, first paragraph, as lacking sufficient written description. Applicants respectfully traverse.

The Office Action indicates that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors were in possession of the claimed invention. By this Amendment, Applicants have amended independent claims 45, 50, 55, and 60 to incorporate the subject matter of dependent claims 66-69, respectively. Consequently, claims 66-69 have been cancelled. Therefore, claims 45, 50, 55, and 60, as amended, recite that the fragment comprises at least five amino acids of SEQ ID NO:1 and has a length selected from the group consisting of 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, and 35 amino acids.

In Applicants' Response submitted to the Patent Office on September 17, 2009, Applicants indicated that the present claims are drawn to polynucleotides encoding HLA binding peptides, and these peptides are linear, as evidenced by pages 11-17 of Fikes *et al.* (see lines 1-3 at page 12 of Chapter 2 in Morse *et al.*, Handbook of Cancer Vaccines, Humana Press: Totowa, New Jersey, 2004) and pages 671-692 of Bradley *et al.* (see paragraph bridging pages 675-676 of Chapter 43 in Majid *et al.*, Advanced Surgical Practice, Greenwich Medical Media: London, 2003). Therefore, the influence of protein folding on antibody-antigen interactions is not relevant to the binding requirements of HLA binding peptides. In response, the current Office Action appears to assert that

because the claims do not recite a maximum size for the HLA binding fragment encoded by the polynucleotide, the size of the HLA binding fragment could approach that of the full-length peptide of SEQ ID NO:1 (1,904 amino acids) and, therefore, the influence of protein folding interactions is relevant. Furthermore, the current Office Action cites Greenspan *et al.* (*Nature Biotechnology*, 17:936-937, 1999) and other references for their teachings concerning the epitopes of antibody-binding peptides. Applicants reiterate that the influence of protein folding on antibody-antigen interactions is not relevant to the binding requirements of HLA binding peptides. Moreover, as indicated above, independent claims 45, 50, 55, and 60 have been amended to recite that the HLA binding fragment has a length selected from the group consisting of 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, and 35 amino acids, which further obviates the stated ground of rejection.

The claimed HLA binding fragments constitute a well defined number of peptides which can be directly excised from SEQ ID NO: 1. Hence, the provision of the entire sequence of SEQ ID NO: 1 provides the necessary starting point for a very simple test where fragments are assayed for their binding to HLA molecules. Given the high level of skill in the polypeptide art and the disclosure of SEQ ID NO:1 in the specification, those of ordinary skill in the art would consider the Applicants to have been in possession of the entire breadth of the claimed genus of polypeptides at the time the application was filed.

Applicants respectfully submit that the specification conveys with reasonable clarity to those of ordinary skill in the art that, as of the application's date, Applicants were in possession of the claimed subject matter. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 45, 47, 50, 52, 55, 57, 60, and 62 are rejected under 35 USC §102(b) as anticipated by Hoffman *et al.* (WO 00/25728). Applicants respectfully traverse. The Office Action indicates that Hoffman *et al.* teach whole genes and the portions of the DNA that constitute protein-encoding genes, including SEQ ID NO:112, which is asserted to have five consecutive amino acids of SEQ ID NO:1. As indicated above, independent claims 45, 50, 55, and 60 have been amended to recite the subject matter of claims 66-69, respectively. Specifically, claims 45, 50, 55, and 60 now recite that the HLA binding fragment has a length selected from the group consisting of 8, 9, 10, 11, 12, 13, 14,

15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, and 35 amino acids. Applicants note that claims 66-69 were not included in this rejection. Applicants also note that SEQ ID NO:112 of the Hoffman *et al.* publication is 1,817 amino acids in length. Therefore, the Hoffman *et al.* publication does not disclose the HLA binding fragment recited in the claims as currently amended.

As the Examiner is aware, to be anticipatory under 35 USC §102(b), a single prior art reference must disclose each and every element as set forth in the claim, either expressly or inherently. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that the Hoffman *et al.* publication does not teach or suggest every element of the claimed polynucleotide. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

Claims 45, 47, 50, and 52 are rejected under 35 USC §102(a) as anticipated by Gardner *et al.* (*Nature*, 2002, 419:498-511). Applicants respectfully traverse. The Office Action asserts that Gardner *et al.* disclose an isolated or purified polynucleotide encoding an antigen binding fragment of SEQ ID NO:1 comprising at least five consecutive amino acids of SEQ ID NO:1. Applicants note that the cited portions of the Gardner *et al.* publication do not appear to disclose a polynucleotide encoding an HLA binding fragment of SEQ ID NO:1 and respectfully submit that the presence of inherent matter must be grounded on more than speculation, it must be a certainty. *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ 2d 1001, 1032-1033 (I.D.KY 1988) (“the doctrine of inherency is available only when the prior inherent event can be established as a certainty. That an event may result from a given set of circumstances is not sufficient to establish anticipation” (emphasis added)). Furthermore, when the reference is silent about the asserted inherent characteristic, while such a gap in the reference may be filled with recourse to extrinsic evidence, the extrinsic evidence

must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 49 USPQ 2d 1949, 1950-1951 (Fed. Cir. 1999).

Moreover, as indicated above, independent claims 45, 50, 55, and 60 have been amended to recite the subject matter of claims 66-69, respectively. Specifically, claims 45, 50, 55, and 60 now recite that the HLA binding fragment has a length selected from the group consisting of 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, and 35 amino acids. Applicants note that claims 66-69 were not included in this rejection.

As indicated above, a reference must disclose each and every element and limitation contained in the rejected claim in order to be anticipatory. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(a) is respectfully requested.

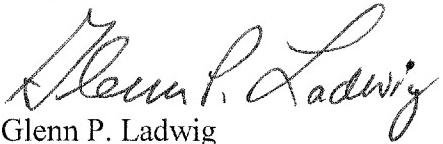
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Glenn P. Ladwig
Patent Attorney
Registration No. 46,853
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

GPL/jnw